REMARKS

Applicant has amended the specification to correct the minor informality at page 10 of the application. Claim 1, 3 and 7 have been amended to overcome the specific rejections made with respect to the claims. Applicant requests reconsideration of the requirement that the polypeptide sequence set forth in the claim by a sequence number. Applicant's claims set forth a specific sequence of amino acids in the peptide.

With respect to the rejection of the claims under 35 U.S.C. § 112 first paragraph on the ground of each of enablement, Applicant respectfully requests reconsideration. Applicant submits that undue experimentation is not required by one skilled in the art.

Under the enablement requirement, "the specification need not explicitly teach those in the art to make and use the invention, the requirement is satisfied if given what they already know, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation'", Amgen Inc. v. Hoechst Marion Roussel, Inc., 65 USPQ 2d 1385.

Initially Applicant wishes to point out with respect to claims 1-5 and 7-10 in each instance a poly peptide sequence is listed. One skilled in the art would know that antibodies may be directed to any number of peptides in this sequence from reading the specification. How peptides may be used to generate antibodies is well known in the art. The Examiner's attention is directed to Cellular and Molecular Immunology Third Edition Abbas, Lichtman and Pober editors, Published by WB Saunders Company, a division of Harcourt Brace & Company 1997 (First edition published in 1991). In this work, there is

an entire chapter on Antigen Processing and Presentation to T lymphocytes. Part of the chapter includes a full explanation of how peptides may be used to generate antibodies. If this publication or any of the other publications cited herein are unavailable to the Examiner, Applicant will provides copies of the relevant sections.

Making vaccines from peptides is a routine process that is just not performed in research. In fact, companies actually offer it as a service. One such company is:

Avecia Biotechnology, UK

(Biologics)

Last update: April 2005

Contact person: Stephen Taylor — Title: Commercial Director, Biologics Unit

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Web-site: www.avecia.com/biotech

The site detailing the amino acids in both the wild type and mutant CCR5 is described by Samson et al (Nature 1996 Volume 382:722-725). This article also describes which amino acids of the CCR5 receptor are embedded in the membrane, and

which are exposed on the surface, and would thus be accessible to attach by an antibody.

Polypeptide based vaccines have been in existence for many years. Their use is described in Chapter 16 of Abbas et al. Another one of the many articles available that discuss polypeptide based vaccines includes Immunogenicity. I. Use of Peptide Libraries to Identify Epitopes that Activate Clonotypic $CD4^+$ T Cells and Induce T Cell Responses to Native Peptide Ligands, *Darcy B. Wilson, Clemencia Pinilla, Dianne H. Wilson, Kim Schroder, César Boggiano, Valeria Judkowski, Jonathan Kaye, Bernhard Hemmer, Roland Martin and Richard A. Houghten*

The Journal of Immunology, 1999, 163: 6424-6434. This publication describes the use of peptides to produce vaccines.

The Examiner's reliance on J Immun (March 2000) 164, 6, 3426-3433 is misplaced in particular with respect to the Examiner's statement. "This is partly due to the fact that naïve B cells that recognize self antigens are destroyed by the immune system during lymphocyte maturation..." on page 5 of the Office Action. This statement is a textbook generalization and is not true. It is based on the assumption that the body's mechanism of Tolerance is 100 percent effective (Tolerance is the mechanism that the body uses to remove all B cells and T Cells that would produce antibodies that would recognize self antigens). Anyone schooled in the art would know that Tolerance is not 100% effective. In the mid 1990's an entire class of diseases were discovered that are referred to as Superantigen Diseases. Among these are Rheumatic Fever and Toxic Shock Syndrome. In these cases it was found that microorganisms were capable of triggering an immune response in which the body produced antibodies that would react

against a body's own antigens. With the discovery of this class of diseases came the realization that Tolerance was not 100%, and that indeed there are B cells and T cells that exist in the body that can be stimulated to produce antibodies to "self antigens".

With respect to the Examiner's claim the Applicant's specification does not provide adequate guidance as to how one skilled in the art would induce antibodies against a sygeneic CCR5 polypeptide, we direct the Examiner's attention to Wilson et al, discussed above which describes the use of peptide to produce autoreactive CD4 cells.

The Examiner relies on Zuber et al. In addition to injecting the CCR5 peptide, this paper also indicated that the CCR5 gene was injected as well. One does not know how this may have affected the number of available binding sites.

The Examiner also relies on Barassi et al. To quote the abstract from the paper

> "These data suggest that immune strategies aimed at generating anti-CCR5 antibodies at the level of the genital mucosa might be feasible and represent a strategy to induce mucosal HIV-protective immunity."

It does not appear from this statement that the authors thought that anti-CCR5 antibodies would be unusually difficult to produce.

In re Sastry, 285 F3d 1378 (Fed Cir 2002) the Federal Circuit affirmed a decision of the Patent and Trademark Office's Board of Appeals that the claims directed to a composition for treating and preventing HIV was enabling. The claims in the application did not identify the specific peptide as Applicant has done. The claims merely recited "a first peptide being a CTL-inducing peptide having the ability to stimulate the

formation or enhance the activity of cylotoxic The cells that are capable of killing MHC-matched target cells that have the peptide on their surfaces. A second peptide was also called for in the claims. This peptide was selected from the group of peptides consisting of an HIV infection-inhibiting peptide derived from the V3 loop of an HIV envelope protein, an HIV infection-inhibiting peptide derived from the N-terminal portion of an HIV envelope protein, an HIV infection-inhibiting peptide derived from the CD4 binding region of an HIV envelope protein, and a The helper cell-inducing peptide characterized as having an amphipathicity value of from about plus 10 to about plus 20, and an alpha helix turn of 100 ± 15 degrees, or a 310 helix turn of 120 ± 15 degrees.

Applicant's claims have provided significantly more specificity than the claims at issue in Sastry.

With respect to the rejection of claim 7 on the ground of lack of enablement because claim 7 does not describe inactivating viral receptors. CCR5 is the viral receptor for the HIV virus and the antibody binding to it will prevent that binding. Smith et al proposed having the body produce antibodies that would bind to sites on the virus. Once these "viral sites" on the virus were bound, this would then prevent the virus from binding to the human cells. This patent application claims the exact opposite, and so is NOT obvious. The vaccine described in this application produces antibodies that block the sites on the human cells that the virus would bind to. Once these sites are blocked, the virus can not bind to the cell.

The Examiner has also objected to the use of the term derivative in the claims. More specifically, the Examiner objects to the language “derivative.”

We direct the Examiner's attention to claim 10 of U.S. Patent No. 4,613,500 where the claim covers "the physiologically active polypeptide or its derivative." Another patent with similar claim language is U.S. Patent No. 4,855,224 (See Claim 19, 21) ("a membrane free derivative of the polypeptide").

CONCLUSION

For the foregoing reasons, Applicant requests reconsideration of the rejection.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing document and fees were mailed by first class mail, postage prepaid, in an envelope addressed to the Hon. Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, this 21st day of November, 2005.

Thomas A. O'Rourke